PTO/SB/21 (09-04)

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission	45

Application Number	10/018,112
Filing Date	December 14, 2001
First Named Inventor	Petersdorf, Effie W.
Art Unit	Not yet assigned
Examiner Name	Not yet assigned
Attorney Docket Number	14538A-005210US

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☒ Communication and Preliminary Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
  - ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
  - ☐ Landscape Table on CD
- ☐ After Allowance Communication to TC
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☒ Other Enclosure(s) (please identify below):
  - Return Postcard
  - Copy of Notice to be returned
  - Sequence Listing - Paper copy and disk
  - Copies of papers previously filed
  - Copy of acknowledgement postcard

Remarks The Commissioner is authorized to charge any additional fees to Deposit Account 20-1430.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Townsend and Townsend and Crew LLP		
Signature	William B. Kezer		
Printed name	William B. Kezer		
Date	5·11·05	Reg. No.	37,369

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.

Signature	Jennifer K. Hardin		
Typed or printed name	Jennifer K. Hardin	Date	5/11/05

Please type a plus sign (+) inside this box → [+]

PTO/SB/21 (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: DEPARTMENT OF COMMERCE

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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	PCT/US00/16722
Filing Date	June 16, 2000
First Named Inventor	Petersdorf, Effie W.
Group Art Unit	Not yet assigned
Examiner Name	Not yet assigned
Total Number of Pages in This Submission: 42	Attorney Docket Number: 14538A-005210US

ENCLOSURES *(check all that apply)*

- [x] Fee Transmittal Form
  - [ ] Fee Attached
- [ ] Amendment / Reply
  - [ ] After Final
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- [ ] Information Disclosure Statement
- [ ] Certified Copy of Priority Document(s)
- [ ] Response to Missing Parts/ Incomplete Application
  - [x] Response to Missing Parts under 37 CFR 1.52 or 1.53
- [ ] Assignment Papers *(for an Application)*
- [ ] Drawing(s)
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- [ ] Petition
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- [ ] Status Letter
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  - Copy of Notice to be returned
  - Communication and Preliminary Amendment
  - Sequence Listing (computer readable copy and paper copy)
  - Declarations

Remarks: The Commissioner is authorized to charge any additional fees to Deposit Account 20-1430.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm and Individual name	Townsend and Townsend and Crew LLP William B. Kezer Reg. No. 37,369
Signature	William B. Kezer
Date	10-21-02

CERTIFICATE OF MAILING

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Typed or printed name	Jennifer K. Hardin		
Signature	Jennifer K. Hardin	Date	10/21/02

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Assistant Commissioner of Patents
Washington, D. C. 20231
On 10/21/02

TOWNSEND and TOWNSEND and CREW LLP

By: Jennifer K. Hardin

PATENT
Attorney Docket No.: 14538A-005210US
Client Ref. No.: 180-14538A-52-1PC

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	Examiner: Not yet assigned
PETERSDORF *et al.*	Art Unit: Not yet assigned
Application No.: PCT/US00/16722	COMMUNICATION UNDER
Filed: June 16, 2000	37 C.F.R. §§ 1.821-1.825
For: OLIGONUCLEOTIDE ARRAYS FOR HIGH RESOLUTION HLA TYPING	AND
	PRELIMINARY AMENDMENT

U.S. Patent and Trademark Office Box PCT
Commissioner for Patents
Washington, D. C. 20231

Sir:

In response to the request to comply with Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures, 37 C.F.R. §§ 1.821-1.825, that accompanied the Notification of Missing Requirements Under 35 U.S.C. 371 in the United States Designated/Elected Office (DO/EO/US) mailed March 22, 2002, Applicants submit herewith the required paper copy and computer readable copy of the Substitute Sequence Listing. Please amend the specification in adherence with 37 C.F.R. §§ 1.821-1.825 as follows.

In the Specification:

Please replace the paragraph beginning at page 15, line 9, with the following:

--The longer chain portion can be any of a variety of molecules which are inert to the subsequent conditions necessary for attaching the oligonucleotide probes, or for hybridization of a sample to the probe array. These longer chain portions will typically be ethylene glycol oligomers containing 2-14 monomer units, diamines, diacids, amino acids, peptides, or combinations thereof. In some embodiments, the longer chain portion is a polynucleotide (*e.g.*, a 15-mer of poly dT; SEQ ID NO:141). Additionally, for use in synthesis of the probe arrays, the linking group will typically have a protecting group, attached to a functional group (*i.e.*, hydroxyl, amino or carboxylic acid) on the distal or terminal end of the chain portion (opposite the solid support). After deprotection and coupling, the distal end is covalently bound to an oligonucleotide probe (*e.g.*, an HLA Class I oligonucleotide probe).--

Please replace the paragraph beginning at page 16, line 24, with the following:

--The length of the spacer between the support and the hybridization sequence influences the efficiency of hybridization (Guo et al, *Nuc. Acids Res.* **22**:5456-5465 (1994)). When large DNA fragments, such as PCR products, are allowed to hybridize with short oligonucleotide probes immobilized on solid supports, adequate distance between the hybridization sequence and the solid surface is required in order to achieve the efficient hybridization. This is due to the steric interference between large DNA molecules and the support. Within one embodiment of the invention, a 15-mer dT spacer (SEQ ID NO:141) was employed in each oligonucleotide probe to provide adequate space between hybridization sequence and the support. Although requiring extra expense in oligonucleotide synthesis, the 15-mer spacer was essential to optimize hybridization signals. Each completed probe contained a 5' amino group for

immobilization chemistry, a 20-nucleotide hybridization sequence, and a 15-mer dT spacer (SEQ ID NO:141) between them.--

Please replace the paragraph beginning at page 28, line 3, with the following:

--Once the solid support has been suitably derivatized, a linking group is attached to provide a spacing between the oligonucleotide probe and the support which is optimized for interactions between the probes and the sample. As provided above, a variety of linking groups can be used in this aspect of the invention. Preferred groups are those that provide a spacing similar to that provided by a 15-mer poly dT spacing group (SEQ ID NO:141). Additionally, the linking group will have a reactive portion that is selected to be compatible with the amino group of the aminoalkylsilane-derivatized support, or with the functional group present on the reagent used to facilitate linking group attachment (*e.g.*, the isothiocyanate portion of 1,4-phenylenediisothiocyanate). Accordingly, at the proximal end (that forming an attachment closest to the support), the linking group will have a functional group that is reactive with an amino moiety (*e.g.*, a carboxylic acid, anhydride, isothiocyanate, and the like) or a functional group that is reactive with an isocyanate, isothiocyanate or carboxylic acid moiety (*e.g.*, an amino group, a hydroxyl group or the like).--

Please replace the paragraph beginning at page 28, line 17, with the following:

--In a particularly preferred embodiment, the support is derivatized first with aminopropyltrimethoxysilane, followed by attachment of 1,4-phenylenediisothiocyanate, followed by attachment of a 15-mer oligonucleotide, preferably a 15-mer of poly-dT (SEQ ID NO:141).--

Please replace the paragraph beginning at page 37, line 1, with the following:

--Exon 2 of HLA-B gene was amplified by two-step asymmetric PCR. In the first step, the PCR primers were Exon 2 5'-primer (5'-GCTCCCACTCCATGAGGTAT-3'; SEQ ID NO:71) and Exon 2 3'-primer (5'-CGGCCTCGCTCTGGTTGTAG-3'; SEQ ID NO:138). The one hundred microliter amplification reaction contained 50 mM KCl, 10 mM Tris-HCl, 1.5 mg MgCl2, 10 mg of gelatin, 20 ng of genomic DNA, 2 microMoles of each primer, 200 microMoles each of dATP, dCTP, dTTP and dGTP, and 2.5 U of Taq DNA polymerase. The amplification reaction was performed in a Perkin-Elmer Cetus 9600 thermal cycler using 35 cycles of the following profile: 94°C for 30 seconds, 60°C for 1 minute and 72°C for 1 minute. The PCR mixture was then purified using a QIAGEN PCR purification kit (QIAGEN Inc., Chatsworth, CA) to remove the excess primers. In the second step, the PCR primer employed was a 5' Rhodamine-labeled Exon 2 3'-primer (SEQ ID NO:138). The PCR was performed in 30 cycles using the following profile: 94°C for 30 seconds, 60°C for 1 minute and 72°C for 2 minutes.--

Please replace the paragraph beginning at page 37, line 14, with the following:

--Amplification of exon 3 of HLA-B was accomplished using Exon 3 5'-primer (5'-ACCCGGTTTCATTTTCAGTTG-3'; SEQ ID NO:139) and Exon 3 3'-primer (5'-CCCACTGCCCCTGGTACC-3'; SEQ ID NO:140). The ampification reaction was performed in 35 cycles of the following profile: 94°C for 30 seconds, 65°C for 1 minute and 72°C for 1 minute. To generate single-strand exon 3 product, the second PCR was performed, employing a 5' Rhodamine-labeled 3 3'-primer (SEQ ID NO:140), in 30 cycles of the following profile: 94°C for 1 minute, 65°C for 1 minute and 72°C for 2 minutes.--

Please cancel the present "SEQUENCE LISTING", pages 1-39, and insert therefor the accompanying paper copy of the Substitute Sequence Listing, page numbers 1 to 27, at the end of the application.

REMARKS

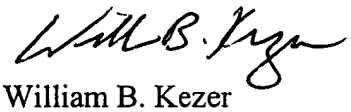
Applicants request entry of this amendment in adherence with 37 C.F.R. §§1.821 to 1.825. This amendment is accompanied by a floppy disk containing the above named sequences, SEQ ID NOS:1-141, in computer readable form, and a paper copy of the sequence information which has been printed from the floppy disk.

The information contained in the computer readable disk was prepared through the use of the software program "FastSEQ" and is identical to that of the paper copy. This amendment contains no new matter.

Attached hereto is a marked-up version of the changes made to the Specification by the current Amendment. The attached pages are captioned "**VERSION WITH MARKINGS TO SHOW CHANGES MADE.**"

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,



William B. Kezer
Reg. No. 37,369

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, 8th Floor
San Francisco, California 94111-3834
Tel: 415-576-0200
Fax: (415) 576-0300
WBK:dmw
SF 1397486 v1

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Specification:

Paragraph beginning at line 9 of page 15 has been amended as follows:

The longer chain portion can be any of a variety of molecules which are inert to the subsequent conditions necessary for attaching the oligonucleotide probes, or for hybridization of a sample to the probe array. These longer chain portions will typically be ethylene glycol oligomers containing 2-14 monomer units, diamines, diacids, amino acids, peptides, or combinations thereof. In some embodiments, the longer chain portion is a polynucleotide (*e.g.*, a 15-mer of poly dT; SEQ ID NO:141). Additionally, for use in synthesis of the probe arrays, the linking group will typically have a protecting group, attached to a functional group (*i.e.*, hydroxyl, amino or carboxylic acid) on the distal or terminal end of the chain portion (opposite the solid support). After deprotection and coupling, the distal end is covalently bound to an oligonucleotide probe (*e.g.*, an HLA Class I oligonucleotide probe).

Paragraph beginning at line 24 of page 16 has been amended as follows:

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adequate space between hybridization sequence and the support. Although requiring extra expense in oligonucleotide synthesis, the 15-mer spacer was essential to optimize hybridization signals. Each completed probe contained a 5' amino group for immobilization chemistry, a 20-nucleotide hybridization sequence, and a 15-mer dT spacer (SEQ ID NO:141) between them.

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Once the solid support has been suitably derivatized, a linking group is attached to provide a spacing between the oligonucleotide probe and the support which is optimized for interactions between the probes and the sample. As provided above, a variety of linking groups can be used in this aspect of the invention. Preferred groups are those that provide a spacing similar to that provided by a 15-mer poly dT spacing group (SEQ ID NO:141). Additionally, the linking group will have a reactive portion that is selected to be compatible with the amino group of the aminoalkylsilane-derivatized support, or with the functional group present on the reagent used to facilitate linking group attachment (*e.g.*, the isothiocyanate portion of 1,4-phenylenediisothiocyanate). Accordingly, at the proximal end (that forming an attachment closest to the support), the linking group will have a functional group that is reactive with an amino moiety (*e.g.*, a carboxylic acid, anhydride, isothiocyanate, and the like) or a functional group that is reactive with an isocyanate, isothiocyanate or carboxylic acid moiety (*e.g.*, an amino group, a hydroxyl group or the like).

Paragraph beginning at line 17 of page 28 has been amended as follows:

In a particularly preferred embodiment, the support is derivatized first with aminopropyltrimethoxysilane, followed by attachment of 1,4-phenylenediisothiocyanate, followed by attachment of a 15-mer oligonucleotide, preferably a 15-mer of poly-dT (SEQ ID NO:141).

Paragraph beginning at line 1 of page 37 has been amended as follows:

Exon 2 of HLA-B gene was amplified by two-step asymmetric PCR. In the first step, the PCR primers were Exon 2 5'-primer (5'-GCTCCCACTCCATGAGGTAT-3'; SEQ ID NO:71 ~~SEQ ID NO: 138~~) and Exon 2 3'-primer (5'-CGGCCTCGCTCTGGTTGTAG-3'; SEQ ID NO:138 ~~SEQ ID NO:139~~). The one hundred microliter amplification reaction contained 50 mM KCl, 10 mM Tris-HCl, 1.5 mg MgCl2, 10 mg of gelatin, 20 ng of genomic DNA, 2 microMoles of each primer, 200 microMoles each of dATP, dCTP, dTTP and dGTP, and 2.5 U of Taq DNA polymerase. The amplification reaction was performed in a Perkin-Elmer Cetus 9600 thermal cycler using 35 cycles of the following profile: 94°C for 30 seconds, 60°C for 1 minute and 72°C for 1 minute. The PCR mixture was then purified using a QIAGEN PCR purification kit (QIAGEN Inc., Chatsworth, CA) to remove the excess primers. In the second step, the PCR primer employed was a 5' Rhodamine-labeled Exon 2 3'-primer (SEQ ID NO:138) ~~(SEQ ID NO 139)~~. The PCR was performed in 30 cycles using the following profile: 94°C for 30 seconds, 60°C for 1 minute and 72°C for 2 minutes.

Paragraph beginning at line 14 of page 37 has been amended as follows:

Amplification of exon 3 of HLA-B was accomplished using Exon 3 5'-primer (5'-ACCCGGTTTCATTTTCAGTTG-3'; SEQ ID NO:139 ~~SEQ ID NO:140~~) and Exon 3 3'-primer (5'-CCCACTGCCCCTGGTACC-3'; SEQ ID NO:140 ~~SEQ ID NO:141~~). The ampification reaction was performed in 35 cycles of the following profile: 94°C for 30 seconds, 65°C for 1 minute and 72°C for 1 minute. To generate single-strand exon 3 product, the second PCR was performed, employing a 5' Rhodamine-labeled 3 3'-primer (SEQ ID NO:140) ~~(SEQ ID NO:141)~~, in 30 cycles of the following profile: 94°C for 1 minute, 65°C for 1 minute and 72°C for 2 minutes ~~minute~~.

UNITED STATES PATENT AND TRADEMARK OFFICE 14538A-005210US

WBK, WC cc: DMW

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U.S. APPLICATION NUMBER NO.	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
10/018,112	Effie W. PETERSDORF	14538A-005210

INTERNATIONAL APPLICATION NO.	
PCT/US00/16722	
I.A. FILING DATE	PRIORITY DATE
06/16/2000	06/17/1999

William B Kezer
Townsend and Townsend and Crew
2 Embarcadero Center
8th Floor
San Francisco, CA 94111

CONFIRMATION NO. 1480
371 FORMALITIES LETTER
OC000000015718115
OC000000015718115

Response Due 5/12/05
NO EXTENSIONS

Date Mailed: 04/12/2005

NOTIFICATION OF DEFECTIVE RESPONSE

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495)

- Priority Document
- Copy of the International Application filed on 12/14/2001
- Copy of the International Search Report filed on 12/14/2001
- Copy of IPE Report filed on 12/14/2001
- Preliminary Amendments filed on 10/28/2002
- Oath or Declaration filed on 10/28/2002
- Biochemical Sequence Listing filed on 10/28/2002
- Request for Immediate Examination filed on 12/14/2001
- U.S. Basic National Fees filed on 12/14/2001

Applicant's response filed 10/28/2002 is hereby acknowledged. The following requirements set forth in the NOTIFICATION of MISSING REQUIREMENTS mailed 03/22/2002 have not been completed.

- This application clearly fails to comply with the requirements of 37 CFR. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998). If the effective filing date is on or after September 8, 2000, see the final rulemaking notice published in the Federal Register at 65 FR 54604 (September 8, 2000) and 1238 OG 145 (September 19, 2000). Applicant must provide an initial computer readable form (CRF) copy of the "Sequence Listing", an initial paper or compact disc copy of the "Sequence Listing", as well as an amendment directing its entry into the application. Applicant must also provide a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d). If applicant desires the sequence listing in the instant application to be identical with that of another application on file in the U.S. Patent and Trademark Office, such request in accordance with 37 CFR 1.821(e) may be submitted in lieu of a new CRF.
- The paper or compact disc copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 CFR 1.821(e). Applicant must provide a substitute paper or compact disc copy of the "Sequence Listing", as well as an amendment directing its entry into the

JE

application OR a substit[redacted]omputer readable form (CRF) copy of the "Se[redacted]nce Listing". These two items must be the same. Applicant must also provide a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d). If the effective filing date is on or after September 8, 2000, see the final rulemaking notice published in the Federal Register at 65 FR 54604 (September 8, 2000) and 1238 OG 145 (September 19, 2000).

- A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 CFR 1.821(e). If the effective filing date is on or after September 8, 2000, see the final rulemaking notice published in the Federal Register at 65 FR 54604 (September 8, 2000) and 1238 OG 145 (September 19, 2000). Applicant must provide an initial computer readable form (CRF) copy of the "Sequence Listing" and a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d). If applicant desires the sequence listing in the instant application to be identical with that of another application on file in the U.S. Patent and Trademark Office, such request in accordance with 37 CFR 1.821(e) may be submitted in lieu of a new CRF.

Applicant is required to complete the response within a time limit of ONE MONTH from the date of this Notification or within the time remaining in the response set forth in the Notification of Missing Requirements, whichever is the longer. No extension of this time limit may be granted under 37 CFR 1.136, but the period for response set in the Notification of Missing Requirements may be extended under 37 CFR 1.136(a).

For questions regarding compliance to 37 CFR 1.821-1.825 requirements, please contact:

- **For Rules Interpretation, call (571) 272-0951**
- **For Patentin Software Program Help, call Patent EBC at 1-866-217-9197 or directly at 703-305-3028 / 703-308-6845 between the hours of 6 a.m. and 12 midnight, Monday through Friday, EST.**
- **Send e-mail correspondence for Patentin Software Program Help @ ebc@uspto.gov**

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

*A copy of this notice **MUST** be returned with the response.*

FRANCINE YOUNG

Telephone: (703) 308-9140 EXT 215

PART 1 - ATTORNEY/APPLICANT COPY

U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	ATTY. DOCKET NO.
10/018,112	PCT/US00/16722	14538A-005210

FORM PCT/DO/EO/916 (371 Formalities Notice)

PTO/SB/21 (05-03)
Approved for use through 04/30/2003. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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First Named Inventor	Petersdorf, Effie W.
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Examiner Name	Not yet assigned
Total Number of Pages in This Submission: 3	Attorney Docket Number: 14538A-005210US

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  Return Postcard
  Statement under 37 CFR 3.73(b)

Remarks: The Commissioner is authorized to charge any additional fees to Deposit Account 20-1430.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual	Townsend and Townsend and Crew LLP William B. Kezer Reg. No. 37,369
Signature	William B. Kezer
Date	6-12-03

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Typed or printed name	Jennifer K. Hardin		
Signature	Jennifer K. Hardin	Date	6/12/03

v

PTO/SB/21 (05-03)
Approved for use through 04/30/2003. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
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Filing Date	June 16, 2000
First Named Inventor	Petersdorf, Effie W.
Art Unit	Not yet assigned
Examiner Name	Not yet assigned
Total Number of Pages in This Submission: 3	Attorney Docket Number: 14538A-005210US

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Date	6-12-03

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